

Inventor : Cawthorne et al.
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REMARKS

Reconsideration of the instant Office Action, entry of the amendments submitted herewith and allowance of all pending claims are respectfully requested.

This amendment is responsive to the Office Action mailed February 8, 2005 (hereinafter the "present Office Action"). Claims 32, 34, 35, 38, 40, 41, 44, 46, 47, 50, 52 and 53 are under examination in the present action. All claims stand rejected.

In response to the present Office Action, claims 32, 38, 40, 44 and 50 have been amended in the present response. No pending claim has been canceled and no new claim has been added. Applicants state that the amendment of claims 32, 38, 44 and 50 does not require any revision of inventorship pursuant to 37 C.F.R. 1.48(b).

1. Applicants are grateful for the withdrawal of the finality of the previous Office Action pursuant to 37 C.F.R. §1.114 and for the entry of the submission of November 23, 2004.

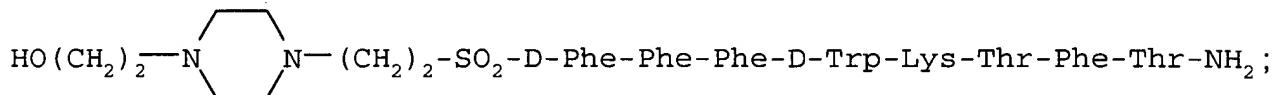
2. Applicants are grateful for the acknowledgement, entry and consideration of the amendment, remarks, terminal disclaimer (TD), information disclosure statement and Form PTO-1449 submitted November 23, 2004. Applicants are further grateful for the withdrawals of the rejection under 35 U.S.C. §112, second paragraph and the rejection based on the judicially-created doctrine of obviousness-type double patenting as set forth in the most previous Office Action.

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3. Claims 32, 34, 35, 38, 40, 41, 44, 46, 47, 50, 52 and 53 have been newly rejected under 35 U.S.C. §102(b) as being anticipated by International Patent Publication WO96/35950 (hereinafter referred to as "WO'950"). Without conceding the correctness of the Examiner's rejection and in an effort solely to advance the prosecution of the instant application to allowance, Applicants have amended claims 32, 38, 44 and 50 to include the limitation that the claimed pharmaceutical compositions include one of the somatostatin analogs which were determined by the Applicants to be somatostatin type-5 receptor selective agonists. Support for this amendment is found at page 12, lines 1-13 of the specification of the instant application, and as such, no new matter has been introduced.

Applicants contend that the rejection of the pending claims under 35 U.S.C. §102(b) is overcome since WO'950 does not teach, infer or suggest that the following compounds, H-Cys-Phe-Phe-D-Trp-Lys-Thr-Phe-Cys-NH₂; H-Cys-Phe-Phe-D-Trp-Lys-Ser-Phe-Cys-NH₂; H-Cys-Phe-Tyr-D-Trp-Lys-Thr-Phe-Cys-NH₂; H-Cys-Phe-Tyr(I)-D-Trp-Lys-Thr-Phe-Cys-NH₂;

and



can be the active ingredient in a pharmaceutical composition comprising a somatostatin type-5 receptor selective agonist, much less that such a composition may be used to lower the

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levels of lipids, triacylglycerols, glycerols or cholesterol in the bloodstream of patients in need thereof. The Court of Appeals for the Federal Circuit, in ruling on the standard for anticipation under 35 U.S.C. §102(b), has stated

[i]t is elementary that an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device,

In re Donohue, 226 U.S.P.Q. 619 (1985); and

. . . exclusion of a claimed element from a prior art reference is enough to negate anticipation by that reference,

Atlas Power Co. v. E. I. duPont DeNemours & Co., 224 U.S.P.Q. 409, 411 (1984). Applicants respectfully submit that claims 32, 38, 44 and 50, as amended, are not anticipated by WO'950, since the cited reference does not contain each and every limitation of the aforementioned amended claims set, as discussed above.

Applicants respectfully request the reconsideration and withdrawal of the rejection of claims 32, 38, 44 and 50 under 35 U.S.C. §102(b), as being anticipated by International Patent Publication WO96/35950.

4. In the instant Office Action, claims 32, 34, 35, 38, 40, 41, 44, 46, 47, 50, 52 and 53 are newly rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. In particular, the Examiner states that the claimed invention is not enabled since "[n]o structure function relationship has been

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established" (**See** present Office Action page 7, lines 9-10).

The Examiner opines that the present claims "would include [various somatostatins or somatostatin agonists] not [having] been shown or taught to be useful or enabled by the disclosed method of...using the invention [and as a result] undue experimentation [would be required to determine] if and under what conditions, the claimed invention as broadly claimed is enabled, since the use of various somatostatins or somatosatins [sic] agonists are contemplated." The Examiner concludes that the claimed invention is, therefore not enabled, since "[t]he results desired appear to be highly dependent on all variables, the relationship of which is not clearly disclosed." Applicants respectfully disagree with the Examiner's opinion and state that at pages 13-16 of the specification of the instant application, a detailed description of an assay used to determine a compound's ability to bind to the five human SSTR receptors is provided together with a table of working examples, and as such, the *In re Wands* factors to determine if the enablement requirement has been met, are clearly present.

Applicants, however, in an effort to solely advance the prosecution of the present application to allowance, have amended claims 32, 38, 44 and 50 to include those compounds tested and determined to be a somatostatin type-5 selective agonists. As such, a "structure function relationship" has been established and all ineffective somatostatin agonists have been excluded from the scope of the pending claims set.

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Applicants respectfully submit that claims 32, 34, 35, 38, 40, 41, 44, 46, 47, 50, 52 and 53 meet the enablement requirement of 35 U.S.C. §112, first paragraph.

Applicants respectfully request the reconsideration and withdrawal of the rejection of claims 32, 34, 35, 38, 40, 41, 44, 46, 47, 50, 52 and 53 under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement.

CONCLUSION

Applicants submit that each ground for rejection asserted by the Examiner in the instant Office Action has been removed. On this basis, it is submitted that claims 11 and 22 are now in a condition for allowance.

Prompt and favorable action is solicited.

Should Examiner Mohamed deem that any further action be desirable with respect to these matters, he is requested to telephone the Applicants' undersigned representative.

The Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-0590.

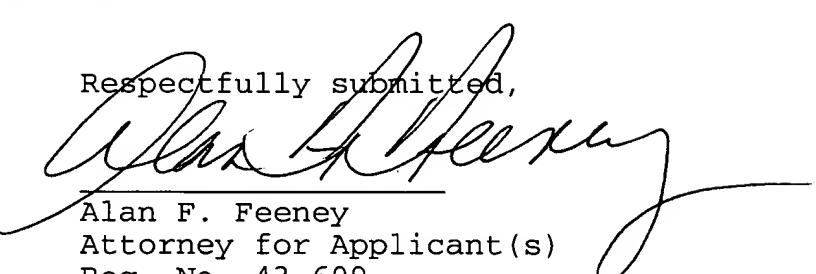
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Respectfully submitted,


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